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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/148,973	09/04/1998	J.TIMOTHY GREENAMYRE	PC10023A	4263

23913 7590 08/15/2003

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NEW YORK, NY 10017-5612

EXAMINER
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BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 08/15/2003

37

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**Application No.  
**09/148,973**Applicant(s)  
**Greenamyre et al**Examiner  
**Maurie G. Baker, Ph.D.**Art Unit  
**1639**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jul 24, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires THREE months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
Please see attached.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_


Claim(s) rejected: \_\_\_\_\_

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☐ Other: \_\_\_\_\_

  
**MAURIE G. BAKER, PH.D.**  
**PRIMARY EXAMINER**  
**ART UNIT 1639**

## ADVISORY ACTION

### *Attachment*

1. Applicant's After Final response filed July 24, 2003 was not found persuasive and thus does not place the case in condition for allowance. The rejections are maintained for reasons of record and the further reasons set forth below.

2. Applicant argues that there is not a reasonable expectation of success when the references are combined. Applicant states that the primary reference "is very specific in naming tardive dyskinesia and tardive dyskinesia only" (page 3, top). The examiner respectfully disagrees. As pointed out in the rejection, Arnold et al teach a number of neurological disorders such as "drug-induced Parkinson's Disease" and other neurological conditions such as "muscular spasms" and "tardive dyskinesia" (see column 1, line 55 through column 2, line 4). The reference teaches that the "use of a neuroprotective agent, such as an AMPA receptor antagonist, is believed to be useful in treating these disorders" (column 2, lines 4-9).

3. Applicant then goes on to specifically describe tardive dyskinesia and other movement disorders and states that "[i]n view of the diverse and multifaceted nature of movement disorders...those of skill in the art could not have predicted that a dyskinesia associated with a dopamine agonist therapy could be effectively treated in the same manner as a dyskinesia associated with a dopamine antagonistic therapy" (pages 3-4). However, the examiner believes that this is a mischaracterization of the reference's

teachings as there is nothing that specifically limits the teachings of Arnold et al to a dyskinesia associated with a dopamine antagonistic therapy. Moreover, the secondary reference, Adams et al, teaches that it was well known in the art at the time of filing that dyskinesia is a side effect associated with dopamine agonist therapy. For example, Adams et al when discussing L-dopa treatment of Parkinson's Disease states that one of the "most common and troublesome effects of L-dopa" is dyskinesia (see page 1073, 1<sup>st</sup> column, 2<sup>nd</sup> full paragraph).

4. Applicant also argues the second rejection under 35 USC 103 stating that the AMPA and NMDA receptor antagonists have very different physiological effects (page 5) and thus the rejection is based on improper hindsight reasoning. The examiner respectfully disagrees. As stated in the Final Office Action, one of ordinary skill would be motivated to use an AMPA receptor antagonist to treat dyskinesia associated with dopamine agonist therapy because Arnold et al teach that blocking AMPA receptors is an effective way to treat neurological disorders, such as dyskinesias and Adams et al teach that one of the "most common and troublesome effects of L-dopa" is dyskinesia. Furthermore, since Stella et al (Papa and Chase) teach that antagonists of the NMDA receptor produce "an ameliorative effect on levodopa-induced dyskinesias" and Arnold et al teach that NMDA and AMPA receptors are subtypes of the *same receptor* then it would be obvious to one of ordinary skill to substitute an antagonist of the AMPA receptor for the antagonist of the NMDA receptor taught by Stella et al.

5. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The examiner maintains that the combined teachings of the cited references indicate information that was within the level of ordinary skill and render the claimed invention *prima facie* obvious.

6. Lastly, applicant's arguments appear to be stating that the results of the claimed method are unexpected. However, as discussed in the Final Office Action, objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results... See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence"). Moreover, applicant's arguments do not rise to the level of factual evidence. See MPEP § 716.01(c): The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Lastly, any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)

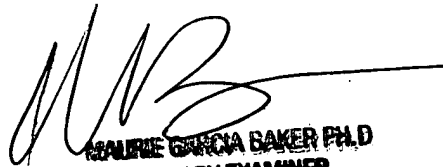
(In MPEP § 716.02). Please note that any evidence filed After Final will *not* be considered unless good and sufficient reasons why it was not earlier presented are shown.

7. For these reasons and the reasons of record, the rejections under 35 U.S.C. 103 are maintained.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.  
August 14, 2003



MAURIE GARCIA BAKER Ph.D.  
PRIMARY EXAMINER